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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,422	04/16/2007	Robert Hes	0218.094.0002	3688

68153 7590 01/04/2012
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EXAMINER

LAWSON, MATTHEW JAMES

ART UNIT	PAPER NUMBER
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3775

MAIL DATE	DELIVERY MODE
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01/04/2012

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,422	Applicant(s) HES ET AL.	
	Examiner MATTHEW LAWSON	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 1-3,5-10,13 and 17 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 1-3,5-10,13 and 17 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Response to Arguments

The Applicant argues that the Vrespa et al. fail to disclose the thread aspect ratio of the two sections (lead portion and tail portion) is not at least about 1.2 and that the ratio of 1.2 is advantageous as "It has been found that a higher thread aspect ratio for the thread on the tail portion can help to make secure screw fixation to cancellous bone." see page 7 of the remarks. The Examiner has taken the position that the value of 1.2 is an optimal value/workable range and it would have been obvious to find the optimal value/range of the screw of Vrespa et al. as the device of Vrespa includes two threaded sections (22 and 24, figure 1) which are used to be inserted into bone. In particular section (24) has smaller higher pitch threading (28) which is optimized for insertion into cortical bone (see column 12, lines 55-67 and column 13, lines 27-33) and has larger lesser pitched threading (26) for insertion into spongy/trabecular/spongy bone (see column 10, lines 43-49, column 11, lines 15-26, column 12, lines 40-54, and column 13, lines 15-26). Accordingly in viewing the specification in light of the figures it even appears that the thread aspect ratio between threads 22 and 24 would be greater than 1 and the device of Vrespa et al. performs the same function as that of the Applicant's (the trailing section being optimized to thread through cortical bone and the leading end to thread through cancellous bone) which the Applicant considers their rationale for the ratio of at least about 1.2. As such the Examiner has not found the Applicant's arguments convincing.

The Applicant further argues that Vrespa in view of Stevens fail to disclose

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“wherein the single-start thread on the tail portion is a continuation of one of the threads of the double-start thread on the lead portion.” The Examiner has relied upon Stevens for the teaching of functional equivalents, that *continuous* and discontinuous threading on a bone screw is well known in the art. Additionally, Stevens teaches the use of multiple helical threads on a single fastener. Further, Stevens explicitly states that interchanging and combining of the disclosed features listed in column 7, lines 65-67 and column 8, lines 1-6 can be accomplished to “form an optimized engager.” Accordingly the Examiner believes that the combination of Vrespa in view of Stevens' listing of potential modifications to form an optimized engager would have been obvious to one of ordinary skill in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 6-10, 12-13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vrespa (US 5,593,410) in view of Bono et al. (US 6,129,730) in further view of Stevens et al. (US 7,811,312).

Regarding claims 1-3, 6-10, 12-13, and 17 Vrespa discloses a bone screw (figure 1) having a lead portion (24, figure 8) and a tail portion (23, figure 8), and an intermediate

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transition portion (22, figure 8), each of the lead portion and the tail portion comprising a root (32-24, figure 1) and a thread (26/28, figure 1), having a thread lead (figure 1) formed on the root, the thread on the lead portion having an approximately constant diameter along a significant portion of its length and tail portion having an approximately constant diameter along a significant portion of its length (figure 1), in which the diameter of the thread on the tail portion is greater than that of the thread on the lead portion (figure 1), and in which the thread lead of the thread on the lead portion is equal to the thread lead of the thread on the tail portion (figure 1), wherein the intermediate transition portion is configured between the threads of the lead portion and the tail portion, and is provided with a diameter that decreases gradually between the thread of the lead portion and the thread of the tail portion (figure 8), wherein the tail portion is provided with a socket end (16, figure 1), wherein the socket end of the tail portion is adapted to be, *i.e. capable*, flush with the surface of the bone or under the surface of the bone after the bone screw is fully inserted, and the thread on the lead portion of the screw is a multi-start thread (column 12, lines 55-58) in which the number of starts of the thread on the lead portion is equal to the ratio of the thread pitch of the thread on the tail portion to the thread pitch of the thread on the lead portion (column 12, lines 63-67), and the thread on the tail portion of the screw is a single-start thread (column 12, line 43), in which the diameter of the root of the tail portion is greater than the diameter of the root of the lead portion (figure 1), and the diameter of the root of the tail portion is greater than the diameter of the root of the lead portion, and has a bore (30, figure 1,

and 74, figure 4-5) extending through it along its length.

Vrespa et al. fail to expressly disclose the lead portion of the screw being a double-start thread and the tail portion of the screw being a single start thread and the pitch of the thread on the trail portion is equal to twice the thread pitch of the thread on the lead portion. Rather, Vrespa et al. teach that the threading on the lead portion of the screw is a multiple of the threading on the tail portion of the screw and having a respective difference in pitch between the respective portions of the screw equal to that multiple (see abstract, column 7, lines 54-67, column 12, lines 63-67).

Bono et al. teach the use of multi-lead/threaded lead portion and a tail portion of the screw having a single start threading. Bono in particular expressly teaches the use of double, triple, quadruple, or quintuple along with "others" (column 3, lines 61-67, column 4, lines 1-3) to provide a screw with the most desirable pull-out values inhibiting pull-out of the screw from cancellous bone (column 3, lines 61-67, column 4, lines 1-3). As such both Bono et al. and Vrespa both use a multi-start threading on the lead portion to remedy the same issue of obtaining the best purchase within the cancellous bone thereby inhibiting pull-out of the screw.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the lead screw portion of Vrespa to have a dual start threading instead of triple start threading as taught by Bono et al. to provide the screw with the most desirable pull-out values to inhibit pulling out of the screw from the cancellous bone region.

Vrespa et al. fail to disclose the claimed invention except that the threading on the trailing portion of the screw is interrupted/discontinuous with the leading portion instead of being continuous with the leading portion. Stevens et al. shows that discontinuous and continuous threading are equivalent structures known in the art (see column 7, lines 65-67 and column 8, lines 1-13). Therefore, because these two threading designs were art-recognized equivalents at the time the invention was made, one of ordinary skill in the art would have found it obvious to substitute the interrupted/discontinuous threading of Vrespa for the continuous threading of Stevens et al.

Regarding claims 1 and 17, Vrespa in view of Bono in view of Stevens disclose the claimed invention except for the ratio of the diameter of the thread on the tail portion to that of the diameter of the thread on the lead portion is at least about 1.2; since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art.

Regarding claims 6-7, Vrespa in view of Bono in view of Stevens disclose the claimed invention except for the ratio of the diameter of the thread on the tail portion to that of the diameter of the thread on the lead portion is at least about 1.2, preferably at least about 1.5, and is not more than about 2.3, preferably not more than about 2.0. It would have been obvious to one having ordinary skill in the art at the time the invention

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was made to have the ratio of the diameter of the thread on the tail portion to that of the diameter of the thread on the lead portion to be at least about 1.2, preferably at least about 1.5, and is not more than about 2.3, preferably not more than about 2.0; since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 9-10, Vrespa in view of Bono in view of Stevens disclose the claimed invention except for the ratio of the diameter of the root on the tail portion to that of the diameter of the root on the lead portion is at least about 1.2, preferably at least about 1.4, and is not more than about 2.3, preferably not more than about 2.0. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the ratio of the diameter of the root on the tail portion to that of the diameter of the root on the lead portion to be at least about 1.2, preferably at least about 1.4, and is not more than about 2.3, preferably not more than about 2.0; since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claims 12-13, Vrespa in view of Bono in view of Stevens disclose the claimed invention except for the ratio of the diameter of the thread aspect on the tail portion to that of the thread aspect ratio on the lead portion is at least about 1.2, preferably at least about 1.35, and is not more than about 2.2, preferably not more than about 2.0. It would have been obvious to one having ordinary skill in the art at the time

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the invention was made to have the thread aspect ratio of the tail portion with respect to the lead portion to be at least about 1.2, preferably at least about 1.35, and is not more than about 2.2, preferably not more than about 2.0; since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Regarding claim 17, Vrespa in view of Bono in view of Stevens discloses the claimed invention except for the root diameter of the lead portion is 4.5 mm and a root diameter of the tail portion is 6.5 mm.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the root diameter of the lead portion is 4.5 mm and a root diameter of the tail portion is 6.5 mm, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vrespa (US 5,593,410) in view of Bono et al. (US 6,129,730) in view of Stevens et al. (US 7,811,312) in further view of Frigg et al. (US 5,180,382).

Vrespa in view of Bono in view of Stevens disclose the claimed invention except for the threading on the tail portion of the screw being a continuation of the one of the threads on the lead portion.

Frigg et al. disclose the threading on the leading portion (7, figure 1) with

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threading and a tail portion (6, figure 1) with threading which is a continuation of the threading on the lead portion (figure 1) to permit continuous threading of the screw allowing for non-stop engagement within the bone/insertion body.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the device of Vrespa in view of Bono in view of Stevens to having continuous threading between the leading and trailing portions of the screw to permit continuous threading of the screw allowing for non-stop engagement within the bone/insertion body as taught by Frigg et al.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to EXAMINER whose telephone number is (571) 270-7375. The examiner can normally be reached on WORK SCHEDULE.

If attempts to reach the examiner by telephone are unsuccessful, ***please contact the examiner's supervisor, Thomas Barrett, at (571) 272-4746.*** The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

If there are any inquiries that are not being addressed by first contacting the Examiner or the Supervisor, you may send an email inquiry to TC3700_Workgroup_D_Inquiries@uspto.gov.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MATTHEW LAWSON/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775

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